



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

March 8, 2000

Hank Juske
Director, Regulatory Affairs
Perkin Elmer Wallac Inc.
3985 Eastern Road
Norton, OH 44203-6215

Dear Mr. Juske:

Your petition requesting the Food and Drug Administration to approve a reclassification petition for Wallac's Neonatal Biotinidase Kit, Models NB-1000, NB-4000 was received by this office on March 8, 2000. It was assigned docket number 00P-0931/CCP 1 and it was filed on March 8, 2000. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe

Dockets Management Branch

00P-0931

ACK1